UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,874	10/30/2001	James Alun Wynne Morgan	13384-002001	1385

7590 08/27/2003

Anita L Meiklejohn
Fish & Richardson
225 Franklin Street
Boston, MA 02110-2804

EXAMINER
PARAS JR, PETER

ART UNIT	PAPER NUMBER
1632	12

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,874	MORGAN ET AL.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *6-11 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-16 and 29* is/are rejected.

7)☒ Claim(s) *1-5 and 17-28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-30 are pending. Claims 1-5 and 17-28 were objected to in the previous Office action and were withdrawn from consideration.

Election/Restrictions

Applicant's election without traverse of Group IV, claims 12-16 and 29, in Paper No. 11 is acknowledged.

Claims 6-11 and 30 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached **N**otice To Comply With Requirements For Patent Applications Containing **N**ucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicants are required to comply with all of the requirements of 37 C.F.R. §§ 1.821 through 1.825. *Any* response to this Office Action, which fails to meet all of these requirements, will be considered non-responsive. The nature of the noncompliance with

the requirements of 37 C.F.R. §§ 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

To avoid damage to a CRF by irradiation, a reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio (**<http://www.uspto.gov/ebc/efs/downloads/documents.htm>**, EFS Submission User Manual - ePAVE)
2. Mailed to: **U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202**
3. Mailed by Federal Express, United Parcel Service or other delivery service to: **U. S. Patent and Trademark Office, 2011 South Clark Place, Customer Window, Box Sequence, Crystal Plaza Two, Lobby, Room 1B03, Arlington, Virginia 22202**
4. Hand Carried directly to the Customer Window at: **2011 South Clark Place, Crystal Plaza Two, Lobby, Room 1B03, Box Sequence, Arlington, Virginia 22202**

Specification

The disclosure is objected to because of the following informalities: It appears that the disclosure is not in compliance with the deposit rules. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. See 37 CFR 1.808.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.808, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a viability statement in accordance with the provisions of 37 CFR 1,807; and

(e) the deposit will be replaced if it should ever become inviable.

As required under 37 CFR 1.809(d), the specification shall contain: (1) the accession number for the deposit; (2) the date of deposit; (3) a description of the deposited biological material sufficient to identify it and to permit its examination; and (4) the name and address of the depository.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-16 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to nucleic acid molecules, including variants thereof, that encode peptides that are nematode control agents. The claims are further directed to methods of producing the same peptides.

The nucleotide sequences that encode peptides that are nematode control agents, including variants thereof, encompassed by the claims have not been disclosed. Based upon the prior art there is expected to be variation among the species of cDNA, which encode nematode control agents, because the sequence of nematode control agent cDNAs would be expected to vary among the different bacterial species producing said peptide control agents. The specification discloses isolation of peptides that encode nematode control agents (SEQ ID NOs: 22 and 23) from *Xenorhabdus* and does not disclose other bacterial nematode control agent peptides or the cDNAs encoding them or other *Xenorhabdus* nematode control agent peptides or cDNAs encoding them or other nematode control agent peptides or cDNAs encoding them from

other cell types. There is no evidence on the record of a relationship between the structure of any nematode agent cDNA and the claimed bacterial nematode control agent cDNA that would provide any reliable information about the structure of other nematode control agent cDNAs within the genus. There is no evidence on the record that the claimed nematode control agent cDNA had a known structural relationship to any other nematode control agent cDNA sequences; the specification discloses only two *Xenorhabdus* nematode control agent peptides; the art indicated that there is variation between nematode control agent cDNA sequences. There is no evidence of record that would indicate that any of the claimed variants of nematode control agents or portions thereof, even have the biological activity of a nematode control agent. In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus, because a *Xenorhabdus* nematode control agent peptide (cDNA) is not representative of the claimed genus. Consequently, since Applicant was in possession of only the *Xenorhabdus* peptides (SEQ ID NOs 22 and 23) and since the art recognized variation among the species of the genus of cDNAs that encode nematode control agents, the *Xenorhabdus* peptides were not representative of the claimed genus. Therefore, Applicant was not in possession of the genus of nematode control agent cDNAs as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient

detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

Claims 12-16 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to nucleic acid molecules, including variants thereof, that encode peptides that are nematode control agents. The claims are further directed to methods of producing the same peptides.

The specification has not taught any variants of the claimed sequences that encode a functional polypeptide that is a nematode control agent. The skilled artisan would not be able to predict the structure of a variant that is biologically active because the specification has not provided any information as to the structural elements required for a nematode control agent to be biologically active. The specification does not provide any information on what amino acid residues are necessary and sufficient for biological activity. The specification also provides no teachings on what amino acid sequence modifications, e.g. insertions, deletions and substitutions, would be permissible in a variant polypeptide that would improve or at least would not interfere with the biological activity or structural features necessary for the biological activity and stability of the protein. Since there are no other examples of a variant known that have

structural homology with SEQ ID NOs: 22 and 23, it is not possible to even guess at the amino acid residues which are critical to its structure or function based on sequence conservation. Furthermore, it is known in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are substituted, and the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable (see Ngo, in The Protein Folding Problem and Tertiary Structure Prediction, Merz et al. (eds.), Birkhauser Boston: Boston, MA, pp. 433 and 492-495, 1994). Rudinger (in Peptide Hormones, Parsons (ed.), University Park Press: Baltimore, MD, pp. 1-7, 1976) discloses that even for peptide hormones, which are much smaller than the instant lipase protein, one cannot predict variant amino acid sequences for a biologically active polypeptide. Rather one must engage in "case to case painstaking experimental study" to determine active variants (see page 7). Consequently, excessive trial and error experimentation would have been required to identify the necessary nucleic acid sequence derivatives encoding a biologically active nematode control agents with an amino acid sequence differing from SEQ ID NOs: 22 and 23 since the amino acid sequence of such polypeptides could not be predicted. Thus, it is not readily apparent to the skilled that any of the claimed variants embraced by the claims have the biological activity of a nematode control agent.

It would have required undue experimentation to predict the structures of variants to the claimed sequences that would be biologically active, without a reasonable expectation of success.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-14 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite as written. The claim requires a nucleic acid that comprises or a degeneratively equivalent sequence or a functional variant. The claim is indefinite as written because the sequence to which the degeneratively equivalent sequence or a functional variant correlate to has not been identified by the claim or the specification. For example, it is not understood from which sequence the variant is derived. Correction is required.

Claim 14 is indefinite as written. The claim requires a variant nucleic acid or amino acid sequence both of which are 70% homologous to an unknown sequence. The claim is indefinite as written because the % homology cannot be determined as the claimed sequences are compared to an unknown sequence. Correction is required.

Claim 29 is incomplete as written. The claim is directed to a method of producing a peptide nematode control agent. The claim is incomplete however, because the steps of the claim do not set forth the goal of the preamble in a positive process. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 12-16 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Geoghegan et al (US 6,006,470).

The claims are directed to nucleic acid molecules, including variants thereof, that encode peptides that are nematode control agents. The claims are further directed to methods of producing the same peptides.

Geoghegan et al teaches the isolation and cloning of cDNAs encoding peptides, particularly lectins that have nematicidal activity. See columns 3-4 and columns 5-6. The nematode control agent cDNAs of Geoghegan et al are broadly interpreted to meet

the variant limitations recited by the claims. Geoghegan et al further teaches expression and production of the protein product of the disclosed cDNAs in transgenic plants. See columns 7-13. The limitations of claim 14 are met by the teachings of Geoghegan et al since the claim requires 70% homology to an unknown nucleic acid sequence. As such no comparison can be made to determine % homology and the term variant as recited by the claim has been broadly interpreted to read on the cDNAs of Geoghegan et al.

Thus, the teachings of Geoghegan et al meet all of the instant claim limitations.

Claims 12-16 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Narva et al (US 5,236,843).

The claims are directed to nucleic acid molecules, including variants thereof, that encode peptides that are nematode control agents. The claims are further directed to methods of producing the same peptides.

Narva et al teaches a nucleic acid molecule encoding a toxin that is toxic to nematodes, wherein the nucleic acid molecule was isolated from *Bacillus thuringiensis*. See the abstract and throughout the entire document. The nucleic acid molecule of Narva is broadly interpreted to meet the variant limitations recited by the claims. Narva et al further teaches a method of producing said toxin. See columns 10-11. The limitations of claim 14 are met by the teachings of Narva et al since the claim requires 70% homology to an unknown nucleic acid sequence. As such no comparison can be

made to determine % homology and the term variant as recited by the claim has been broadly interpreted to read on the nucleic acid molecules of Narva et al.

Thus, the teachings of Narva et al meet all of the instant claim limitations.

Claims 12-16 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Jarrett et al (WO 98/08388).

The claims are directed to nucleic acid molecules, including variants thereof, that encode peptides that are nematode control agents. The claims are further directed to methods of producing the same peptides.

Jarrett et al teaches a nucleic acid molecule encoding a toxin that has insecticidal properties, wherein the nucleotide sequence was isolated from *Xenorhabdus*. See pages 2-3. The nucleic acid molecule of Jarrett et al is broadly interpreted to meet the variant limitations recited by the claims. Jarrett et al further teaches a method of producing said toxin. See pages 22-25. The limitations of claim 14 are met by the teachings of Jarrett et al since the claim requires 70% homology to an unknown nucleic acid sequence. As such no comparison can be made to determine % homology and the term variant as recited by the claim has been broadly interpreted to read on the nucleic acid molecules of Jarrett et al.

Thus, the teachings of Jarrett et al meet all of the instant claim limitations.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

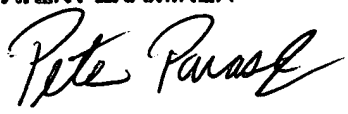
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

Art Unit 1632

PETER PARAS
PATENT EXAMINER



Application No.:09/889,874

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [X] 7. Other: Figure 2 comprises an unidentified sequence; the statement required under 1.821(f) was not submitted by a registered patent agent.

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support (SIRA)
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE